MAY 01 2002

K021073

SMDA 510(k) SUMMARY

VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF TYPE V

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers:	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF-TYPE V
Common Name:	Nasopharyngoscope (flexible) and accessories
Classification:	21 CFR 874.4760 Nasopharyngoscope (flexible) and accessories, Class II
Predicate Device:	XENF-TP (K# 013591)

D. Description of the Device(s)

The subject device is used for endoscopic diagnosis and treatment within the nasal and nasapharyngeal lumens. The optical system is modified from the image guide to CCD and the resolution is improved.

Following is the comparison table between the subject ENF-V and the predicate XENF-TP.

Specifications	Subject Device ENF-V	Predicate Device XENF-TP
Field of view	90°	85°
Direction of view	0° (Forward)	0° (Forward)
Depth of field	5 - 50 mm	3 – 50 mm
Insertion tube working length	365mm	365mm
Insertion tube outer diameter	ϕ 3.9mm	ϕ 5.0mm
Bending section angulation range	Up130° ,Down130°	Up130° ,Down130°
Total length	593mm	620mm
Optical system	CCD	Image guide
Resolution (Max, Minimum)	12.6 Lines/mm 12.6 Lines/mm	5.62 Lines/mm 0.70 Lines/mm

<modified specification>

- Field of view is wider.
- Total length is shorter.
- Optical system is CCD which provides observation on a monitor.
- Resolution is improved.

The subject device, ENF-V, has the following similarities to the predicate device which has received 510(k) clearance.

- The same intended use
- The same operating principle except for the optical system
- The same reprocessing method
- The same basic endoscope design except for the optical system
- The same body contacting materials

In summary, the subject device, ENF-V, described in this submission is substantially equivalent to the predicate device.

E. Intended Use of the Device(s)

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the nasal and nasapharyngeal lumens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 01 2002

Olympus America Inc.
c/o Laura Storms-Tyler
Two Corporate Center Drive
Melville, NY 11747

Re: K021073
Trade/Device Name: Olympus ENF Type V
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: March 29, 2002
Received: March 2, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

OLYMPUS

Indications for Use Statement

510(k) Number(if known): ~~Not assigned yet.~~ K021073

Device Name: VISERA RHINO-LARYNGOVIDEOSCOPE OLYMPUS ENF TYPE V

Indications for Use:

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the nasal and nasopharyngeal lumens.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K021073

Prescription Use ✓ OR Over-The-Counter Use

(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)